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Title

A prospective cohort study on the impact of smoking on soft tissue alterations around single implants

Running title

Soft tissue alterations around single implants in smokers

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Authors

Stefanie Raes, Antonio Rocci, Filiep Raes, Lyndon Cooper, Hugo De Bruyn, Jan Cosyn

Affiliations and institutions

Raes S¹ DDS; Rocci A² MD, DDS; Raes F¹ DDS, MSc, PhD; Cooper L³ DDS, MSc, PhD
De Bruyn H¹⁻⁴ DDS, MSc, PhD; Cosyn J^{1,5} DDS, MSc, PhD.

1 Department of Periodontology and Oral Implantology, Dental School, Faculty of Medicine and Health Sciences, University of Ghent, Ghent, Belgium

2 Private practice, Chieti, Italy

3 Department of Prosthodontics, University of North Carolina School of Dentistry, Chapel Hill, NC, USA

4 Department of Prosthodontics, Faculty of Odontology, Malmö University, Malmö, Sweden

5 Department of Periodontology, Dental Medicine, Faculty of Medicine and Pharmacy, Free University of Brussels (VUB), Brussels, Belgium

Contact address corresponding author

Stefanie Raes

University of Ghent, Faculty of Medicine and Health Sciences, Dental School,
Department of Periodontology and Oral Implantology, De Pintelaan 185, B-9000 Ghent,
Belgium

E-mail: stefanie.raes@ugent.be

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Abstract

Objectives: To compare smokers to non-smokers in terms of soft tissue alterations following single implant treatment in healed bone.

Material and methods: Non-smoking and smoking patients with sufficient bone volume in need of a single implant in the anterior maxilla (15-25) were consecutively recruited in 3 centres. Conventional single implant surgery was performed and an immediate provisional crown was installed. Eight to 12 weeks later, the latter was replaced by a permanent one (baseline). Papilla regrowth and midfacial recession was registered after 2 years of function.

Results: The sample consisted of 39 non-smokers (21 females; mean age 42) and 46 smokers (22 females; mean age 45). Smokers had 3 **early** failures whereas all implants integrated successfully in non-smokers. Statistically significant papilla regrowth was observed in non-smokers (**mesial** 0.63 mm, **distal** 0.75 mm), whereas smokers showed stable papillae (between cohorts: $p \leq 0.025$). Midfacial soft tissue level demonstrated statistically significant overgrowth in non-smokers (0.53 mm), whereas it remained stable in smokers (between cohorts: $p = 0.004$).

Conclusion: Smokers failed to demonstrate papilla regeneration and showed more midfacial recession following single implant treatment when compared to non-smokers.

INTRODUCTION

Smoking has a tremendous impact on human health. Johnson et al. (2000) reviewed the local and systemic problems associated with smoking (Johnson & Bain 2000). According to a survey conducted by the World Health Organization in 2009 26-31 % of the population in the USA or Western Europe are smokers. Thus, smokers may be a considerable group of patients in need of a single implant.

Recent systematic reviews have demonstrated survival rates surpassing 95% for single implants up to five years of function (Creugers et al. 2000, Berglundh et al. 2002, den Hartog et al. 2008, Jung et al. 2012). However, none of these reviews accounted for smoking habits, even though smoking has been identified as a risk factor for implant loss and peri-implant inflammation (Hinode et al. 2006, Strietzel et al. 2007). Interestingly, the influence of the implant location in smokers seems of pivotal importance with implants located in the maxillary arch being more prone to failure (Hinode et al. 2006, Strietzel et al. 2007). Also with respect to peri-implant bone loss smokers seem to be worse off than non-smokers and again, disparities mainly occur in the maxillary arch (Vandeweghe & De Bruyn 2011, Vervaeke et al. 2012). This has been confirmed in a recent multifactorial analysis (Vervaeke et al. 2013).

To the best of our knowledge, only one systematic review on conventionally-installed single implants reported on soft tissue outcome and aesthetics (den Hartog et al. 2008). However, no information could be found on smoking habits. On the other hand, smokers may demonstrate impaired wound healing (Javed et al. 2012). This could have its effects on linear and even volumetric soft tissue changes following implant surgery. Clinical studies are clearly needed to investigate this hypothesis.

The aim of this 2-year prospective study was to compare the overall outcome of immediately loaded single implants in non-smokers and smokers with a focus on soft tissue alterations. The research hypothesis was that smokers would demonstrate less papilla regrowth and more midfacial recession compared to non-smokers.

MATERIAL AND METHODS

Patient selection

The present study was designed as a multicenter, prospective clinical trial and included referred patients in need of a single implant in the anterior maxilla (15 – 25). Patients were consecutively recruited between April 2005 and November 2007 in a private dental clinic in Italy and two academic dental clinics (University Hospital Ghent, Belgium and North Carolina, USA). The inclusion and exclusion criteria are listed in table 1. The study protocol was approved by the Ethics Committees of each participating center and conducted according to the Helsinki declaration of 1975 as revised in 2000.

Cohorts

The patients were divided into two cohorts according to their smoking habits: smoker and non-smoker. A patient was registered as a smoker when smoking 10 or more cigarettes a day as reported by the patient at intake.

Surgical procedure

Prior to implant placement, analgesics (800 mg ibuprofen) and antibiotics (1 g Amoxicillin or 300 mg Clindamycin in case of penicillin allergy) were administered. Patients rinsed with 15 ml of 0.12 % chlorhexidine digluconate for 30 seconds. Implants (ASTRA TECH Implant System OsseoSpeed™, DENTSPLY Implants, Mölndal, Sweden) were placed in a healed ridge (at least 3 months following tooth extraction) of the anterior maxilla (15 – 25) under local anesthesia and following manufacturer's guidelines. Depending on the facial tissue dimension, a conventional full thickness flap or a flapless procedure was performed. This decision was left to the discretion of the surgeon. In case of flap surgery, single sutures were applied.

Postoperative instructions included mouth rinsing (Chlorhexidine digluconate 0.12 %, twice daily for 10 days), gentle brushing and a soft diet during 21 days. When considered necessary by the clinician, analgesics or antibiotics were supplied. Oral hygiene instructions were given. Sutures were removed after 7 days.

Prosthetic procedure

Immediately after implant placement, an appropriate abutment was selected according to the position of the bone level and the height of the gingiva. Direct Abutments (DENTSPLY Implants, Malmö, Sweden) were seated. Provisional acrylic resin crowns were fabricated chairside. Following polishing, crowns were installed with glass ionomer cement and cement remnants were removed. Care was taken to avoid all occlusion and articulation.

Eight weeks following implant placement, final impressions were made using standard procedures (open tray impression technique using polyether impression material (Impregum, 3MEspe, ST. Paul, MN, USA). Appropriate prosthetic materials (metal fused to porcelain restoration or full-ceramic restoration) were selected for each individual patient. Permanent crowns were installed within four weeks after impression taking. Upon crown installation, care was taken to avoid cement remnants. Only light occlusion and articulation was allowed.

Papilla regrowth and midfacial recession

A calibration session was held before the start of the study. Duplicate registration of papilla regrowth and midfacial recession was performed in one center with a 3-week interval, which allowed to calculate intra-examiner repeatability.

Papilla changes were registered at the mesial and distal aspect of each implant at 2 years with permanent crown placement as a reference time point. The perpendicular distance from the top of the papilla to a line connecting the incisal planes of both adjacent teeth was used as a basis for calculating papilla changes over time (Fig. 1). Distances were registered using a manual periodontal probe (Hu-Friedy, Chicago, Illinois, USA) to the nearest 0.5 mm.

Midfacial recession was registered for each implant at 2 years with permanent crown placement as a reference time point. The distance from the midfacial peri-implant mucosa to the incisal plane of the permanent implant crown was used as a basis for

calculating midfacial recession over time (Fig. 1). Again, a manual probe was used for registration.

Implant survival and marginal bone changes

An implant was considered a survival when it was present regardless of its clinical condition.

Marginal bone changes were registered at the mesial and distal aspect of each implant at 2 years with permanent crown placement as a reference time point. The distance from the implant-abutment interface to the first bone-to-implant contact as assessed on peri-apical radiographs (long-cone paralleling technique) was used as a basis for calculating marginal bone changes over time. Distances were recorded to the nearest 0.1 mm under seven times magnification using a magnification glass. Mesial and distal distances were averaged to receive 1 value per implant and per time point. All measurements were made by an independent radiologist.

Statistical analysis

The patient was the statistical unit in all analyses. If more than one implant was placed in a patient one implant was randomly chosen. Descriptive statistics included frequency distributions for categorical variables (gender, failing implants) and mean values and standard deviations for continuous variables (age, mesial and distal papilla regrowth, midfacial recession, marginal bone loss). **Intra-examiner repeatability on papilla regrowth and midfacial recession was evaluated by means of intra-class correlation coefficient (ICC).** Within-cohort differences in continuous variables were analyzed using the paired samples T-test. Between-cohort differences were analyzed using the independent samples T-test. Disparities between cohorts in terms of gender and failing implants were analyzed using the Fisher's exact test. The level of significance was set at 0.05.

RESULTS

Descriptive analysis

Of the 94 patients that met the selection criteria, 85 were finally included in the analysis. In the non-smoking group 8 implants (in 7 patients) needed guided bone regeneration as judged peroperatively, and 2 implants (in 1 patient) could not be immediately loaded. In the smoking group 1 implant could not be immediately loaded. Eleven patients were lost to follow-up at 2 years (2 non-smokers, 1 female and 1 male, age range 37 - 38; 9 smokers, 3 females and 6 males, age range 25 - 61). Table 2 shows demographical details of both cohorts. There were no statistically significant differences between smokers and non-smokers for gender ($p=0.665$) and age ($p=0.363$). Patients in the smoking group smoked 10 to 30 cigarettes a day with a mean of 17. All patients in the non-smoking group were absolute non-smokers.

Papilla regrowth and midfacial recession

Intra-examiner repeatability of papilla regrowth and midfacial recession was excellent amounting to an ICC of 0.876 ($p < 0.001$) and 0.989 ($p < 0.001$), respectively.

Whereas papillae showed statistically significant regrowth in non-smokers (mesial 0.63 mm, distal 0.75 mm; $p < 0.001$), papillae remained stable in smokers ($p \geq 0.386$). The disparity between smokers and non-smokers (distal 0.77 – mesial 0.97 mm) was statistically significant ($p \leq 0.025$).

Similarly, midfacial soft tissue level showed statistically significant overgrowth in non-smokers (0.53 mm; $p < 0.001$) whereas it remained stable in smokers ($p = 0.229$). The disparity between smokers and non-smokers (0.63 mm) was statistically significant ($p = 0.004$).

Implant survival and marginal bone changes

Two years after implant placement, the overall implant survival rate was 100 % for non-smokers and 93.5 % for smokers ($p = 0.246$). Two implants in 2 patients were removed 2 weeks after placement because of pain. One implant was lost after 2 months because of non-integration.

Whereas non-smokers showed stable marginal bone levels over the 2-year period ($p = 0.148$), smokers demonstrated statistically significant bone loss of 0.22 mm ($p = 0.014$). The disparity between smokers and non-smokers was statistically significant (0.55 mm; $p = 0.025$).

DISCUSSION

To the best of our knowledge, this is the first prospective cohort study describing the impact of smoking on soft tissue alterations around single implants in the anterior maxilla. The level of evidence of such a study may be considered high given the fact that a randomised controlled trial would be impossible to conduct due to obvious ethical restrictions.

An important finding of this study was that non-smokers demonstrated significant papilla regrowth over the 2-year observation period. This is in accordance with other clinical studies on immediately loaded single implants (Hall et al. 2007, Cooper et al. 2010, Raes et al. 2011, Vandeweghe et al. 2012). However, as described in a recent overview this may not be a consistent finding (De Bruyn et al. 2013). Vandeweghe et al. (2012) showed minor, yet significant papilla reduction at the distal aspect, which could be related to the fact that the vast majority of the sample consisted of periodontal patients (Vandeweghe et al. 2012). In a clinical study up to 5 years, Donati et al. (2013) demonstrated stable papilla levels (Donati et al. 2013). Interestingly however, non-smokers as well as smokers had been included. It could be hypothesized that smoking negatively influenced papilla regeneration. At least on the basis of the present study, smokers did not demonstrate substantial papilla gain, which is in clear contrast to the findings in non-smokers.

A similar observation was found for midfacial soft tissue level in favour of non-smokers. That is, non-smokers showed on average 0.63 mm less midfacial recession than smokers. To the best of our knowledge, comparative data have not been published in the oral implant literature. On the other hand, there are at least 3 large cross-sectional

epidemiological studies with multivariate analyses identifying smoking as a risk indicator for recession around teeth (Susin et al. 2004, Toker & Ozdemir 2009, Sarfati et al. 2010).

The present study showed an overall survival rate of 96.5 % after 2 years of function. This is in accordance with a number of systematic reviews on single implant treatment (Creugers et al. 2000, Berglundh et al. 2002, den Hartog et al. 2008, Jung et al. 2012). Although not statistically significantly different, smokers had 3 failures whereas all implants integrated successfully in non-smokers. At least 2 systematic reviews have identified smoking as a risk factor for implant failure (Hinode et al. 2006, Strietzel et al. 2007). Obviously, the present study may have been underpowered to demonstrate a significant impact of smoking on implant survival.

Marginal bone loss was another secondary outcome variable in this study and amounted to a mean disparity of 0.55 mm in favour of non-smokers. This finding is in agreement with at least one systematic review (Strietzel et al. 2007) and a number of large clinical studies (Vandeweghe & De Bruyn 2011, Vervaeke et al. 2012, Vervaeke et al. 2013).

A number of limitations should be taken into account when interpreting the results of present study. First, a classical treatment concept was used. That is, single implants were installed in healed bone. Additional prospective cohort studies are needed to elucidate the impact of smoking on soft tissues dynamics following other treatment concepts and in case of multiple tooth loss. Second, early soft tissue alterations prior to the installation of the permanent crown were not registered. This could not be done since the crown was used as a reference for soft tissue registration. Evidently, provisional crowns may differ substantially from permanent crowns. Only with a stent this could have been overcome. Third, a dosage and duration dependent effect of smoking on the prevalence of recession around teeth has been shown (Susin et al. 2004, Toker and Ozdemir 2009). Unfortunately, dosage and duration of smoking were not registered in this study. Fourth, there were 11 dropouts in this study for various reasons. Two non-smokers and 9 smokers dropped out leading to possible selective

lost to follow up. Fifth, patients did not evaluate treatment outcome in terms of soft tissues. Hence, it is unclear to what extent patients perceive the observed soft tissue disparities between smokers and non-smokers as disturbing. On the other hand, the appreciation of the aesthetic outcome is usually rated higher by patients than by clinicians, underlining the fact that clinicians are more critical in this appraisal (Chang et al. 1999, Cosyn et al. 2013).

CONCLUSION

Smokers failed to demonstrate papilla regeneration and showed more midfacial recession following single implant treatment when compared to non-smokers.

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